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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 22

Application Number: 09/331,554
Filing Date: 8/23/1999
Appellant(s): Russel et al.

Michael D. Smith

For Appellant

EXAMINER'S ANSWER

This is in response to appellant's brief on appeal filed 9/10/2001.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The brief does not contain a statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief. Therefore, it is presumed that there are none. The Board, however, may exercise its discretion to require an explicit statement as to the existence of any related appeals and interferences.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

Claims 13-16, 19-21, 24-26, 29 and 30 are pending and are being appealed.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

Appellant's brief includes a statement that the claims 13-16, 19-21, 24-26, 29 and 30 do not stand or fall together and provides reasons as set forth in 37CFR 1.192(c)(7) and (c)(8).

Appellants have grouped the claims as follows:

A. Claims 13, 14, 16, 20, 21 and 24.

B. Claims 15, 25 and 26.

C. Clams 19, 29 and 30.

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

The following is a listing of the prior art of record relied upon in the rejection of claims under appeal.

4,379,170	Hettinga et al.	4-1983
5,573,947	Madec et al.	11-1996

10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 U.S.C. § 102

Although the appellants have not properly argued the claims according to their groupings, the examiner will respond to arguments as if the appellants have properly argued the groups. Therefore, only the broadest claim of each group A, B and C will be carefully addressed below.

Claims 13-16, 19-21, 24-26, 29 and 30 remain rejected under 35 U.S.C. 102(b) as being anticipated by US 4,379,170.

The claims are directed to a dietary composition comprising propionibacteria at concentration more than 10^9 cells per gram and to a method of making this composition. Some claims are further drawn to incorporation of additional bacteria such as lactic bacteria into the

dietary composition. Some claims are further drawn to incorporation of the dietary composition into a food product such as cheese. The propionibacteria in the dietary composition have the capability to produce nitric oxide in physiologically significant quantities *in vivo* to improve intestinal function.

US 4,379,170 teaches a composition comprising propionibacteria and lactic bacteria such as Swiss or Emmental cheeses and a method of making this composition, wherein concentration of propionibacteria in the dietary composition is more than 10^9 cells per gram. For example: see the amounts of the propionibacteria strains P16 and P20 (col. 9, lines 45, 50-52; col. 10, lines 13).

The cited compositions and method of making the compositions are considered to anticipate the claimed invention because the dietary compositions in the cited reference comprise identical amounts (more than 10^9 cells per gram) of identical bacteria (propionibacteria) as required by the claims. And, thus, the compositions of the cited reference which have the identical bacteria in identical amounts may be reasonably considered to inherently possess the ability to produce nitric oxide as required by the claims. Moreover, the cited reference teaches the use of the propionibacteria strain "P20" in a food product or in a method of making food product, for example: cheese. According to appellants' disclosure, the strain P20 has been considered by appellants as capable of producing nitric oxide (see specification page 8, lines 16-20 and page 4, lines 13-15). Therefore, the cited patent appears to anticipate the claimed invention.

A. The argument concerning the Group A, the broadest claims of the group being 13 and 20, is rebutted below.

The main appellants' argument (brief pages 16-17, 20-23) is that the cited prior art fails to teach or suggest the ability of propionibacteria to produce nitric oxide (NO). This is not found convincing because both the composition and the method claims require the presence or incorporation of the identical bacteria in the same range of concentrations in Example 2, namely at least 10^9 cells of propionibacteria per gram. The capability of propionibacteria to produce NO is an inherent property of these bacteria regardless of whether or not production of NO by propionibacteria has been taught or suggested in the prior art.

The propionibacteria in the composition of the cited reference would reasonably be expected to produce physiologically significant quantities of NO, *in vivo*, to effect intestinal function. This is because: 1) the bacterial strain that is present in the cited reference of US'170 (P20) is the same strain that has been shown to be capable of producing NO, *in vitro*, (page 8, lines 16-29 and page 4, lines 13-15); and 2) the results obtained, *in vivo*, are also dependent upon the quantity of the foodstuff consumed. Thus, even a strain, which produces, *in vitro*, a relatively lesser amount of NO than another strains, when consumed in sufficient quantity, would reasonably be expected to be capable of producing sufficient NO to effect intestinal function. The claims are not limited to any specific strain or dosage.

In order to qualify as an anticipatory reference, the disclosure need not ~~be~~ express the inherent property. Even failure of those skilled in the art to contemporaneously recognize an inherent property,

function or ingredient of a prior art reference does not preclude a finding of anticipation: In *Atlas Powder Co. v. IRECO, Inc.*, 51 USPQ2d 1943 (Fed. Cir. 1999). Thus appellants are incorrect in arguing that the anticipatory rejection is improper.

The result or effect of the same procedure by using the same bacterial cultures at the same amount is reasonably expected to be same. See *Ex parte Novitski*, 26 USPQ2d 1389 (Bd. Pat. App. & Inter. 1993). The board rejected a claim directed to a method for protecting a plant from plant pathogenic nematodes by inoculating the plant with a nematode inhibiting strain of *P. cepacia*. A US patent to Dart disclosed inoculation using *P. cepacia* bacteria for protecting the plant from fungal disease. Dart was silent with regard to nematode inhibition, but the Board concluded that nematode inhibition was an inherent property of the bacteria, and therefore of the method as disclosed by Dart.

Appellants' arguments are further directed to limitations which are not required by the broadest claims 13 or 20.

Appellants argue that the cited method of cheese making as disclosed by US '170 requires the use of some elevated temperature and/or cooking/pasteurizing processes which might result in the killing of propionibacteria, and, thus, the viable amount of propionibacteria would not be capable/sufficient to release NO (see brief on appeal at page 16, last paragraph, for example). This is not found convincing. Since the ability of producing NO is an inherent property of the propionibacteria of the cited reference, it is considered that the propionibacteria, when present in a viable state, are inherently capable to produce/release NO

as intended for the claimed invention. The cited patent US' 170 teaches the use of propionibacteria in the form of viable starter cultures intended for further fermentation and making of a fermented product such as cheese (example 2). The process of example 2 requires a maximum temperature of 124°F in the presence of the propionibacteria. This is a mild temperature, well below pasteurizing temperature of 180°F, and is not considered to be extreme enough to kill the propionibacteria. It is noted that one of appellants' claimed food products is cheese and that no evidence has been presented that demonstrates that the cheese of Example 2 does not contain at least 10^9 cells of propionibacteria per gram of cheese. In fact, the appellants admit that a mature cheese contains about 10^9 cells/gram of propionibacteria (specification page 2, line 31).

Another argument, drawn to limitations which are not designated by the invention of the broadest claims of the group A, is that propionibacteria requires NO precursors such as nitrate and/or nitrite in order to be able to produce/release NO (see appeal brief page 17 par. 4, for example). However, ~~the~~ none of the claims requires either incorporation of NO precursors nor measuring amounts of NO. None of the claims requires the presence of nitrate in the compositions in order to trigger release of NO by propionibacteria as argued. Even dependent claim 14, which is further argued (brief pages 24-29), is directed to a composition wherein the propionibacteria are capable of releasing particular amounts of nitric oxide, if nitrates are available. But dependent claim 14 does not require incorporation of components of the Yeast Extract medium in the dietary compositions/methods of making the dietary compositions.

B. The argument concerning the Group B claims 15, 25 and 26 is rebutted below.

The difference between the Group A claims and the Group B claims is that the composition of Group B indicates a list of food products including a cheese product, for example. The cited US'170 clearly teaches the presence or incorporation of propionibacteria in a fermented product or cheese products. The arguments concerning the lack of disclosure of the inherent capability of propionibacteria to produce physiologically significant amounts of NO to improve intestinal function in the cited reference and to the intended effects of the compositions/methods are repetitive (brief pages 29-36) and they have been addressed above.

C. The argument concerning the Group C claims 19, 29 and 30 is rebutted below.

The difference between the Group C claims and the claims of the other Groups is that Group C requires the presence of bifidobacteria and lactobacteria in the compositions and methods of making the compositions. The combined use of bifidobacteria and lactobacteria together with propionibacteria in food compositions and method of making food composition such as cheese, for example, have been known in the art and it has been clearly taught in the cited US'170 (example 2 at col. 10, lines 12-13). The arguments concerning the lack of disclosure of the inherent capability of propionibacteria to produce physiologically significant amounts of NO to improve intestinal function in the cited reference and to the intended effects of the compositions/methods are repetitive (brief pages 44-49) and they have been addressed above.

Claims 13-16, 20, 21, 24-26 and 28 remain rejected under 35 U.S.C. 102(b) as being anticipated by US 5,573,947.

The claims are directed to a composition and to a method of making this composition comprising propionibacteria at concentration about or more than 10^9 cells per gram of the composition. Some claims are further drawn to composition being food product. The propionibacteria in the dietary composition have the capability to produce nitric oxide in physiologically significant quantities *in vivo* to improve intestinal function.

US 5,573,947 teaches a composition intended for counting viable propionibacteria in various biological samples wherein both the samples and the final compositions inoculated with the samples contain propionibacteria of about or more than 10^9 cells per gram. Some of the disclosed biological samples are Emmental or Morbier cheeses which are taught as containing more than 10^9 CFU/g or more than 10^9 viable cells of propionibacteria per gram (see table 3). Some of the disclosed compositions are compositions comprising medium components and propionibacteria derived from various samples (table 1) wherein the final amount of propionibacteria of about or more than 10^9 cells per gram. The cited patent also discloses a method of making the compositions with propionibacteria by providing a supply of propionibacteria such as a sample of milk or cheese or pure propionibacteria and mixing the supply into various compositions including edible components such as drink (milk) or unfermented preparation (water, milk) or dehydrated preparation (cheese, solid components of the medium) and etc., for example: see col. 5, lines 30-55.

The compositions of propionibacteria in the cited reference and methods of making the compositions in the cited reference are considered to anticipate the claimed invention because both compositions and method of making compositions encompass incorporation of identical components such as propionibacteria at identical amounts such as 10^9 cells per gram. The capability of propionibacteria to produce nitric oxide is an inherent property of propionibacteria. Moreover, the cited reference teaches the use of propionibacteria identified as *Propionibacterium acidipropionici* and *Propionibacterium freudenreichii* strains CNRZ 81, CNRZ 89, CNRZ 277, NCDO 1072, CNRZ 86, CNRZ 80 and LS 2502 (LABO STRADA 2502) (see table 1 at col. 8) which are identical to particular cultures capable of releasing nitric oxide (see specification page 16, lines 1-10). Thus, the cited patent appears to anticipate the invention as claimed.

A. The argument concerning Group A, broadest claims 13 and 20 is rebutted below.

The main appellants' argument (brief pages 16-23) is directed to the idea that the cited prior art fails to teach or suggest the ability of propionibacteria to produce nitric oxide (NO). This is not found convincing because both the composition clam 13 and method claims 20 and 21 require the presence or incorporation of the identical bacteria at identical amounts as is disclosed in the composition and method of the cited reference, that is at least 10^9 cells of propionibacteria per gram. The capability of propionibacteria to produce NO is an inherent property of these bacteria regardless of whether or not production of NO by propionibacteria has been taught or suggested in the prior art. The bacteria of the compositions would

reasonably be expected to inherently express same activity particularly in the light of the fact that the cited compositions and methods comprise incorporation of the identical amounts of propionibacteria. The propionibacteria in the composition of the cited reference would reasonably be expected to produce physiologically significant quantities of NO, *in vivo*, to effect intestinal function. This is because: 1) the bacterial strains of the cited patent US'947 (Madec et al.) are identical to the bacterial strains which have been shown to be capable of producing NO, *in vitro*, (see page 16 and Figures 10-12); and 2) the results obtained, *in vivo*, are also dependent upon the quantity of the foodstuff consumed. Thus, even a strain, which produces *in vitro* a relatively lesser amount of NO than another strains, when consumed in sufficient quantity, would reasonably be expected to be capable of producing sufficient NO to effect intestinal function. The claims are not limited to any specific strain or dosage.

In order to qualify as an anticipatory reference, the disclosure need not ~~be~~ express the inherent property. Even failure of those skilled in the art to contemporaneously recognize an inherent property, function or ingredient of a prior art reference does not preclude a finding of anticipation: In

Atlas Powder Co. v. IRECO, Inc., 51 USPQ2d 1943 (Fed. Cir. 1999). Thus appellants are incorrect in arguing that the anticipatory rejection is improper.

The result or effect of the same procedure by using the same bacterial cultures at the same concentration is reasonably expected to be same. See *Ex parte Novitski*, 26 USPQ2d 1389 (Bd. Pat. App. & Inter. 1993). The board rejected a claim directed to a method for protecting a plant from plant pathogenic nematodes by inoculating the plant with a nematode inhibiting strain of *P. cepacia*. A US patent to Dart disclosed inoculation using *P. cepacia* bacteria for protecting the plant from fungal disease. Dart was silent with regard to nematode inhibition, but the Board concluded that nematode inhibition was an inherent property of the bacteria, and therefore of the method as disclosed by Dart.

Appellants' arguments are further directed to limitations which are not required by the broadest claims 13 or 20.

With regard to the medium composition of US'947 appellants appear to argue that the cited compositions encompass incorporation of some compounds (antibiotics, for example) which might affect viability of the propionibacteria and, thus, the inherent property of the propionibacteria to produce NO (brief page 18, par. 1, for example). However the cited patent US'947 demonstrates that propionibacteria at the same amount of 10^9 cells per gram as required by the claims have been successfully cultured in the compositions with antibiotics, and, therefore, these propionibacteria are viable and, thus, capable of any and all inherent properties.

Appellants' argument that propionibacteria requires NO precursors or nitrogen sources (nitrite or nitrate) in order to be able to produce/release NO (see appeal brief page 20, par. 4, for example) is not persuasive because none of the claims requires either incorporation of NO precursors nor measuring amounts of NO. Dependent claim 14, which is further argued (brief pages 24-29), is directed to a composition wherein the propionibacteria are capable of releasing particular amounts of nitric oxide, if nitrogen source are available, but dependent claim 14 does not require incorporation of Yeast Extract Lactate (YEL) medium components into the dietary composition. Moreover, the cited patent US '947 appears to teach the use of similar "YEL" medium components (example 1) including at least some nitrogen source in the compositions with propionibacteria.

B. The argument concerning the Group B claims 15, 25 and 26 is rebutted below.

The appellants' arguments concerning inherent property of propionibacteria to produce NO in the composition and method of the cited reference are repetitive (brief pages 31-36) and they have been addressed above. The difference between the Group A claims and the Group B claims is the fact that Group B claims a propionibacteria composition is in a food product including cheese and milk, for example. The cited US '947 (Madec et al.) teaches the presence or incorporation of the propionibacteria in various dietary products, for example: cheese (table 3) or unpasteurized milk (col. 3, lines 37-39); thus, the claimed composition is anticipated. With regard to other arguments related to viability of the propionibacteria, it is

noted that the cited US'947 clearly teaches that the propionibacteria are viable in the dietary compositions such as a final cheese product wherein the propionibacteria are present in amounts of 10^9 cells per gram as required by the claimed invention in order to produce physiologically significant amounts of NO to effect intestinal function (see Emmental and Morbier cheeses at table 3).

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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November 30, 2001.

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